DETAILED ACTION

Response to Arguments

- 1. Applicant's arguments filed 07/25/2008 have been fully considered but they are not persuasive. The Following reasons are why:
- 2. First, Applicants states that during the Interview on July 1st, 2008, the Examiner stated that reciting the steps to the method in the specific order would overcome the 102 and 103 rejections. This is incorrect.
- 3. The Examiner agreed that reciting the method in a specific order <u>may</u> overcome the 102 rejection. All parties <u>did agree</u> that the proposed amendments to the claims <u>may not</u> overcome new 103 rejections to Collier et al.
- 4. Second, Applicants' state that there would be no motivation for introducing a pause step into the method of Collier et al. The Examiner respectfully disagrees. Collier et al discloses a "cap" which forms part of a sealed vessel that contains a fluid. The "cap" is elastomeric (See Column 4 lines 37-43). Collier et al also discloses that the vessel is at a lower pressure than the atmosphere (as disclosed in this section by the movement of air into the vessel). Collier et al does also disclose the problem of tearing occurring of some caps (not all caps tear because this only happens when Dimension® System caps and vessels are used emphasis added in the context of where this is found See Column 4 lines 43-46. It would have been obvious to one of ordinary skill in the art at the time the invention was made to introduce a pause step for many reasons 1). To prevent tearing of caps when the Dimension® System cap is used; 2). To prevent the fluid which is under vacuum from being expelled through the opening made by the

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fluid transfer device when the atmosphere rushes into the vessel. These are very two

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clear reasons (i.e. - motivation) why to include a pause step in the method of Collier et

al.

5. Applicants' argued during the interview that the probe tears the cap and therefore

can not possibly teach the recited claimed invention. A more careful look at this section

of Collier et al actually discloses that tearing ONLY happens when Dimension® System

caps and vessels are used. There is nothing in the Collier et al reference that discloses

that ALL caps are torn (as Applicant argued was the case during the interview). In fact,

to support this statement Collier et al actually discloses that the cap reseals itself after

the fluid transfer device is removed (Please see Column 2 lines 60-63) which reads,

6. "(d) withdrawing the probe from the container and allowing the puncture

area to reseal (heal) preventing reagent degradation."

7. This clearly demonstrates that not all caps **tear** during the insertion of the fluid

transfer device. The Dimension® System is only a preferred sealed vessel and cap and

is explicitly stated that it is not critical to the method (See Column 3 lines 55-60).

8. Applicants' argue that the Examiner does not provide any support that a slower

speed would be essential to the method of Collier et al. This would be apparent to one

of ordinary skill in the art a the time the invention was made because penetrating an

elastomeric cap where the atmosphere within the vessel is evacuated, would cause fluid

to be expelled from the vessel through the opening if the equalizing atmospheric

pressure rushes into the vessel (-the probe punctures the cap at a high speed). One of

ordinary skill in the art would know that slowly allowing atmosphere into the sealed

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vessel (note - that is under vacuum) would prevent the movement of the fluid towards the top of the vessel and thus prevent contamination of the probe, the outside of the vessel and outside of the cap.

- 9. Applicants argue that the Examiner's reasoning is unsupported by the facts and constitutes impermissible hindsight reconstruction. The Examiner respectfully disagrees. The Examiner is relying on <u>basic simple common sense</u> which one of ordinary skill in the art would have. Further, Collier et al disclose problems (i.e.- tearing) which are a teaching and motivation to include steps that were omitted in the method.
- 10. Finally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).
- 11. Applicant's arguments with respect to claims 1-7 and 9-34 have been considered but are most in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 14. Claims 1, 2, 18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al.
- 15. Applicants' claims are toward a method.
- 16. Regarding Claims 1, 2, 18, & 20, Collier et al discloses the automated method for removing a fluid substance from a sealed collection device comprising A). A <u>cap fitted onto</u> an open-end of a fluid-holding vessel (See Figure 2 Items 10 & 12), the method comprising the <u>following ordered</u> steps: A) Puncturing the cap with a fluid transfer device (See Figure 2; B); C). Contacting the fluid substance <u>with the fluid transfer</u> device (See Figure 2 B, C, & D); D). Drawing at least a portion of the fluid substance into the fluid transfer device (See Figure 2 note: aspirate); and E). Removing the fluid transfer device from the collection device (See Figure; E). Collier et al does not disclose step B). Pausing movement of the fluid transfer device prior to contacting a fluid substance contained in the vessel. Collier et al does however disclose allowing air to be vented from the collection device (See Column 4 lines 39-43). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

Collier et al and include a pause movement of the fluid transfer device prior to contacting a fluid substance contained in the vessel to allow the elastomeric cap to reseal around the fluid transfer device before continuing to enter the fluid, to minimize disrupting the fluid by the influx of atmosphere into the vessel, as well as prevent the fluid from being splashed up and out of the opening made by the fluid transfer device (Collier et al discloses this limitation; See Arguments above- applicant has amended the claim for this intended purpose, air is vented from the vessel during equilibration), and prevent the tearing of the cap only when the Dimension® System cap is used (note: the method of Collier et al is not limited to the Dimension® System caps as argued by the Applicant during the interview on July 1st, 2008. Please see response to Arguments for support for this information).

- 17. Additional Disclosures Included: <u>Claim 2</u>: The method of claim 1, wherein the fluid substance is obtained from a biological fluid selected from the group consisting of blood, urine, saliva, sputum, mucous or other bodily secretion, pus, amniotic fluid, cerebrospinal fluid and seminal fluid (See Column 2 line 22); <u>Claim 18</u>: The method of claim 1, wherein the cap contains a wick for limiting the release of an aerosol from the vessel during step A). (See Column 3 lines 61-66); <u>Claim 20</u>: The method of claim 18 further comprising penetrating a seal affixed to the cap with the fluid transfer device, wherein the seal maintains the wick within the cap (See Column 3 lines 61-66).
- 18. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in view of Köster et al (WO00/60361).

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19. Applicants' claims are toward a method.

- 20. Regarding Claim 3, Collier et al discloses the method of claim 1, except wherein the fluid transfer device is a plastic pipette tip. Collier et al does however disclose that the probe is provided with an outer sleeve to support its sideway movement when stretching the lid (*emphasis* on "stretching" not tearing). Köster et al discloses a fluid transfer device to be used in an automated method for removing a fluid from a sealed container (See Abstract & Figure 1 & Page 24 lines 3-5) that may be used with disposable pipette tips (See Page 24 lines 18-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al with the pipette tips of Köster et al because this would limit the amount of cross contamination between reagents and samples observed and controlled by a wash solution of Köster et al (See Page 24 lines 15-17). Further it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a plastic pipette tip because the plastic would be much less reactive to the reagents and samples being transferred by Köster et al (See Page 24 lines 17).
- 21. Claims 4, 5, & 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in view of Köster et al (WO00/60361) and Seto (US5874048).
- 22. Applicants' claims are toward a method.
- 23. Regarding Claims 4, 5, & 7, Collier et al in combination with Köster et al, disclose the method of claim 3, except wherein the pipette tip includes one or more ribs extending outwardly from an outer surface thereof, and wherein at least one of the ribs

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contacts a surface of the cap during step A). Seto et al discloses the formation of a rib

either on the pipette tip or lid (See Column 3 lines 27-36) for use in a method of

removing a fluid from a fluid from a sealed vessel. It would have been obvious to one of

ordinary skill in the art at the time the invention was made to modify the pipette tip of

Köster et al to have ribs, of any number because according to Seto et al, these ribs may

be of any shape and size as long as it can nullify the pressure difference between the

space inside of the container and the space outside (See Column 3 lines 28-30).

24. Additionally it would have been obvious to one of ordinary skill in the art at the

time the invention was made to modify Collier et al with a pipette tip with any number of

ribs because pipette tips with varying number of ribs were available for automated

processes of fluid transfer at the time of the invention and this would further prevent

cross contamination and carry over problems as recited in Collier et al (See Column 2

lines 19-21).

25. Additional Disclosures Included: Claim 5: Wherein the pipette tip includes one or

more grooves recessed from an outer surface thereof, and wherein at least one air

passageway is formed between at least one of the grooves and the surface of the cap

during step a). (See Column3 lines 28-30); Claim 7: wherein the cap includes one or

more radially extending ribs and wherein at least one of the ribs contacts the fluid

transfer device during step A). (See Column 3 lines 11-14).

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- 26. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in combination with Köster et al and in further view of Sandhage (US2906423).
- 27. Applicants' claim is toward a method.
- 28. Regarding Claim 6, the combination of Collier et al and Köster et al disclose the method according to Claim 3, except wherein prior to Step A). , a lubricant is applied to at least a portion of the pipette tip or the surface of the cap punctured during step A). Sandhage discloses the method that utilizes a lubricant to puncture an enclosure using a needle (i.e.- a needle may define a type of stainless steel probe). It would have been obvious to one of ordinary skill at the time the invention was made to modify the method from the combination of Collier et al and Köster et al with Sandhage because according to Sandhage, this application of lubricant would allow for easy insertion of the tip through the cap and also fills up the cut slit thereby preventing the entry of contaminating microorganisms (Column 2 lines 52-57).
- 29. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al.
- 30. Applicants' claims are toward a method.
- 31. Regarding Claim 9, Collier et al discloses the method of Claim 1, except wherein the movement of the fluid transfer device is paused for at least about 0.5 seconds during step b). Collier et al does implicitly disclose that a time period is needed to allow an elastomeric material of the cap to open during penetration (See Column 4 lines 39-43). It would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the method of Collier et al to include a pause time of 0.5 seconds during the puncture of the lid because Collier et al discloses that different materials will require a longer pause time to create a "leak" within the lid (See Column 4 lines 50-53).

- 32. For Claim 10, Collier et al discloses the method of claim 1 except further comprising a step of withdrawing the fluid transfer device from the punctured surface of the cap between steps a) and c). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al and include a withdrawal of the fluid transfer device from the punctured surface of the cap between steps a) and c) because Collier et al suggests that the best placement for penetrating the cap would be at the center axis, which would allow for the greatest depth or withdrawal of the tip between steps a) and c)however, the location of puncture may be changed as desired (See Column 4 lines 59-63). Further it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al and include a step of withdrawing the fluid transfer device from the punctured surface of the cap between steps a) and c) because elastomeric materials contain higher and lower density areas which may not allow for the probe to puncture completely and this would result in the operator attempting to locate a different section of the lid to puncture.
- 33. For Claim 11, Collier et al discloses the method of claim 10, except wherein the movement of the fluid transfer device is paused for at least about 0.5 seconds during step b). Collier et al does implicitly disclose that a time period is needed to allow an

elastomeric material of the cap to open during penetration (See Column 4 lines 39-43). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al to include a pause time of 0.5 seconds during the puncture of the lid because Collier et al discloses that different materials will require a longer pause time to create a "leak" within the lid (See Column 4 lines 50-53).

- 34. For Claim 12, Collier et al discloses the method of Claim 1, except, wherein the speed of the fluid transfer device during step c) is greater than the speed of the fluid transfer device during step a). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al to vary the speed of the fluid transfer to be slower during step a) and faster during step c because if the sealed container contains a large pressure difference between the environment and the inside of the container, the contents are likely to be explosively forced out through the punctured opening and contaminate the environment.
- 35. For Claim 13, Collier et al discloses the method of claim 12 except further comprising withdrawing the fluid transfer device from the punctured surface of the cap between steps a) and c). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al and include a withdrawal of the fluid transfer device from the punctured surface of the cap between steps a) and c) because Collier et al suggests that the best placement for penetrating the cap would be at the center axis, which would allow for the greatest depth or withdrawal of the tip between steps a) and c) however, the location of puncture may be changed as desired (See Column 4 lines 59-63). Further it would have been obvious to

one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al and include a step of withdrawing the fluid transfer device from the punctured surface of the cap between steps a) and c) because elastomeric materials contain higher and lower density areas which may not allow for the probe to puncture completely at one location and this would result in the operator attempting to locate a different section of the lid to puncture.

- 36. For Claim 14, Collier et al discloses the method of claim 12, except wherein the movement of the fluid transfer device is paused for at least about 0.5 seconds during step b). Collier et al does implicitly disclose that a time period is needed to allow an elastomeric material of the cap to open during penetration (See Column 4 lines 39-43). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al to include a pause time of 0.5 seconds during the puncture of the lid because Collier et al discloses that different materials will require a longer pause time to create a "leak" within the lid (See Column 4 lines 50-53).
- 37. For Claim 15, Collier et al discloses the method of claim 14, except for further comprising withdrawing the fluid transfer device from the cap between steps a) and c). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al and include a withdrawal of the fluid transfer device from the punctured surface of the cap between steps a) and c) because Collier et al suggests that the best placement for penetrating the cap would be at the center axis, which would allow for the greatest depth or withdrawal of the tip between steps a) and c) however, the location of puncture may be changed as desired (See Column 4

lines 59-63). Further it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al and include a step of withdrawing the fluid transfer device from the punctured surface of the cap between steps a) and c) because elastomeric materials contain higher and lower density areas which may not allow for the probe to puncture completely at one location and this would result in the operator attempting to locate a different section of the lid to puncture.

- 38. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in view of Koch (US5578272).
- 39. Applicants' claim is toward a method.
- 40. Regarding Claim 16, Collier et al discloses the method of Claim 1, except wherein the cap comprises a molded plastic having a generally conical inner wall and wherein the inner wall is punctured by the fluid transfer device during step A). Collier et al does however disclose that the method may be used with different sealed vessels and caps (See Dimension® System and also discloses problems associated with different sealed vessels and caps (See Column 1 line 63 to Column 2 line 43). Koch et al discloses a fluid transfer apparatus/system with a cap comprising plastic molded cap in the form of a generally conical inner wall (See Figure 7 Item 81 & Column 3 lines 53-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al with the apparatus and sealed vessels and caps of Koch because the holder for the containers of Koch (See Figure 1 Item 12), provides the necessary stability Collier et al recommends to secure the sealed

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vessels and caps against to prevent sideway motion (See Collier et al Column 4 lines

54-56).

41. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et

al, in view of Koch et al and Seto et al (US5874048).

42. Applicants' claim is toward a method.

43. Regarding Claim 17, Collier et al in combination with Koch disclose the method

of Claim 16, except wherein the inner wall includes a plurality of radially extending

striations. Seto et al discloses a fluid transfer device wherein the cap or the pipette may

have striations on at least one or the other (See Column 3 lines 11-36). It would have

been obvious to one of ordinary skill in the art at the time the invention was made to

modify the combination of Collier et al and Koch et al with the teachings of Seto et al to

allow equilibration of the pressure within the sealed container with the environment (See

Column 3 lines 26-31).

44. Claims 1 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Collier et al in view of Levy (US6054099).

45. Applicants' claims are toward a method.

46. Regarding Claims 1 & 18 Collier et al discloses the method of Claims 1 & 18,

except wherein the wick is selected from the group consisting of pile fabrics, sponges,

foams, felts, sliver knits, and spandex. Collier et al does however disclose that the cap

that have an elastomeric layer of suitable material (See Column 3 lines 61-66). Levy et

al discloses a fluid transfer device which is used on combination with a container with an elastic sheet of foam plastic (See Column 4 lines 67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al with the elastic sheet of foam plastic from Levy et al because according the Collier et al, the cap construction is not important, so long as it is elastomeric (See Column 3 line 67 to Column 4 line 2).

- 47. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in view of Koch, and in further view of Levy.
- 48. Applicants' claim is toward a method.
- 49. For Claim 19, Collier et al in combination with Koch disclose the method of Claim 16, except wherein the wick is selected from the group consisting of pile fabrics, sponges, foams, felts, sliver knits, and spandex. Collier et al does however disclose that the cap that have an elastomeric layer of suitable material (See Column 3 lines 61-66). Levy et al discloses a fluid transfer device which is used on combination with a container with an elastic sheet of foam plastic (See Column 4 lines 67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al with the elastic sheet of foam plastic from Levy et al because according the Collier et al, the cap construction is not important, so long as it is elastomeric (See Column 3 line 67 to Column 4 line 2).
- 50. Claims 21, 22, & 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al.

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51. Applicants' claims are towards a method.

52. Regarding Claim 21, Collier et al discloses the automated method for removing a fluid substance from a sealed collection device comprising a cap fitted onto an open end of a fluid-holding vessel (See Figure 2 Items 10 & 12) the method comprising the following ordered steps: A). Puncturing the cap with a fluid transfer device (See Figure 2 B); C). Contacting the fluid substance with the fluid transfer device (See Figure 2B-D); D). Drawing at least a portion of the fluid substance into the fluid transfer device (See Figure 2 Aspirate); and E). Removing the fluid transfer device from the collection device (See Figure 2 E). Collier et al does disclose step B). Wherein the fluid transfer device enters the collection device (See Figure 2). Collier et al does not disclose B). Increasing the speed of the fluid transfer device to a second speed as it enters the collection device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the speeds to the movement of the automated system of Collier et al to prevent degradation of the fluid samples being analyzed in Collier et al (atmosphere contains oxygen which acts to oxidize bodily fluids such as blood - Collier et al Column 2 lines 20-23), to limit the contact exposure of the probe to the fluid sample to prevent contamination of the fluid and sample from adhering to the probe surface, to lessen the exposure and prevent contact of the fluid to airborne microbes which are introduced during the equilibration (venting) in the method of Collier et al, to prevent tearing of the cap as disclosed when only those particular sealed vessels and caps are used, and to increase efficiency of the automation of Collier et al during the analysis of the sample.

60-65).

53. Additional Disclosures Included: <u>Claim 22:</u> Wherein the fluid substance is obtained from a biological fluid selected from the group consisting of blood, urine, saliva, sputum, mucous or other bodily secretion, pus, amniotic fluid, cerebrospinal fluid and seminal fluid (See Column 2 line 22); <u>Claim 30:</u> Wherein the cap contains a wick for limiting the release of an aerosol from the vessel during step A). (See Column 3 lines

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in view of Köster et al (WO00/60361).

- 54. Applicants' claim is toward a method.
- 55. Regarding Claim 23, Collier et al discloses the method of Claim 21, except wherein the fluid transfer device is a plastic pipette tip. Collier et al does however disclose that the fluid transfer device is a stainless steel probe. Köster et al discloses a fluid transfer device to be used in an automated method for removing a fluid from a sealed container (See Abstract & Figure 1 & Page 24 lines 3-5) that may be used with disposable pipette tips (See Page 24 lines 18-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al with the pipette tips of Köster et al because this would limit the amount of cross contamination between reagents and samples observed and controlled by a wash solution of Köster et al (See Page 24 lines 15-17). Further it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a plastic

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pipette tip because the plastic would be much less reactive to the reagents and samples being transferred by Köster et al (See Page 24 lines 17).

- 56. Claims 24, 25, & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in view of Köster et al (WO00/60361) and Seto (US5874048).
- 57. Applicants' claims are toward a method.
- 58. Regarding Claims 24, 25, & 27 Collier et al in combination with Köster et al, disclose the method of claim 23, except wherein the pipette tip includes one or more ribs extending outwardly from an outer surface thereof, and wherein at least one of the ribs contacts a surface of the cap during step A). Seto et al discloses a fluid transfer device wherein a formation of a rib is either on the pipette tip or lid (See Column 3 lines 27-36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pipette tip in the combination of Collier et al and Köster et al to have ribs, of any number because according to Seto et al, these ribs may be of any shape and size as long as it can nullify the pressure difference between the space inside of the container and the space outside (See Column3 lines 28-30), which solves the problem of Collier et al that attempts to equalize the pressure within the sealed container and outside the container using a sideways motion.
- 59. Additional Disclosures Included: <u>Claim 25</u>: wherein the pipette tip includes one or more grooves recessed from an outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and a surface of the cap during step A). (See Column 3 lines 28-30); <u>Claim 27</u>: Wherein the cap includes one or

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more radially extending ribs positioned on a surface of the cap, and wherein at least one of the ribs contacts the fluid transfer device during step a) (See Rejections above).

60. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in view of Koch (US5578272).

- 61. Applicants' claim is toward a method.
- 62. Regarding Claim 28, Collier et al discloses the method of Claim 21, except wherein the cap comprises a molded plastic cap having a generally conical inner wall, and wherein the inner wall is punctured by the fluid transfer device during step a). Collier et al does however disclose that the method may be used with different sealed vessels and caps (See Dimension® System and also discloses problems associated with different sealed vessels and caps (See Column 1 line 63 to Column 2 line 43). Koch et al discloses a fluid transfer apparatus/system with a cap comprising plastic molded cap in the form of a generally conical inner wall (See Figure 7 Item 81 & Column 3 lines 53-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Collier et al with the apparatus and sealed vessels and caps of Koch because the holder for the containers of Koch (See Figure 1 Item 12), provides the necessary stability Collier et al recommends to secure the sealed vessels and caps against to prevent sideway motion (See Collier et al Column 4 lines 54-56).

63. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al, in view of Koch et al and Seto et al (US5874048).

- 64. Applicants' claim is toward a method.
- 65. Regarding Claim 29, Collier et al in combination with Koch disclose the method of Claim 16, except wherein the inner wall includes a plurality of radially extending striations. Seto et al discloses a fluid transfer device wherein the cap or the pipette may have striations on at least one or the other (See Column 3 lines 11-36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Collier et al and Koch et al with the teachings of Seto et al to allow equilibration of the pressure within the sealed container with the environment (See Column 3 lines 26-31).
- 66. Claims 31 & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al in view of Levy (US6054099).
- 67. Applicants' claims are toward a method.
- 68. Regarding Claim 31, Collier et al discloses the method of Claim 30, except wherein the wick is selected from the group consisting of pile fabrics, sponges, foams, felts, sliver knits, and spandex. Collier et al does however disclose that the cap has an elastomeric layer of suitable material (See Column 3 lines 61-66). Levy et al discloses a fluid transfer device which is used in combination with a container with an elastic sheet of foam plastic (See Column 4 lines 67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of

Collier et al with the elastic sheet of foam plastic from Levy et al because according the Collier et al, the cap construction is not important, so long as it is elastomeric (See Column3 line 67 to Column 4 line 2).

- 69. Additional Disclosures Included: <u>Claim 32</u>: The method of claim 30 further comprising penetrating a seal affixed to the cap with the fluid transfer device, wherein the seal maintains the wick within the cap (See Levy, Abstract).
- 70. Claims 33 & 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al.
- 71. Applicants' claims are toward a method.
- 72. Regarding Claims 33, & 34, Collier et al discloses the method of claim 21, except wherein A). The second speed is at least twice the first speed or B). Wherein the first speed is from about 15 mm/s to about 60 mm/s. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the speeds to the movement of the automated system of Collier et al to prevent degradation of the fluid samples being analyzed in Collier et al (atmosphere contains oxygen which acts to oxidize bodily fluids such as blood Collier et al Column 2 lines 20-23), to limit the contact exposure of the probe to the fluid sample to prevent contamination of the fluid and sample from adhering to the probe surface, to lessen the exposure and prevent contact of the fluid to airborne microbes which are introduced during the equilibration (venting) in the method of Collier et al, to prevent tearing of the cap as disclosed when

only those particular sealed vessels and caps are used (where tearing is involved), and to increase efficiency of the automation of Collier et al during the analysis of the sample.

Telephonic Inquiries

73. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bobby Ramdhanie/ Examiner, Art Unit 1797 /B. R./

/Walter D. Griffin/ Supervisory Patent Examiner, Art Unit 1797